



Attorney's Docket No. 035780/233666

APR 16 2005  
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Talarico *et al.* Confirmation No.: 8297  
Appl. No.: 09/934,300 Group Art Unit: 1645  
Filed: 8/21/01 Examiner: S. Devi  
For: METHODS FOR PURIFICATION OF AN ACTIVATED PEG SOLUTION AND  
FOR THE SYNTHESIS OF A MODIFIED HEMOGLOBIN SOLUTION

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**COMMUNICATION TO EXAMINER**

Please find attached copies of citation nos. 16-19 as filed in the U.S. Patent and Trademark Office on September 17, 2004. These citations are submitted in response to your request in the Final Office Action mailed November 16, 2004.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 14, 2004.

Pamela Lockley

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Substitute for form 1449/PTO  
(Revised 04/2003)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**  
Application Number 09/934,300  
Filing Date 8/21/01  
First Named Inventor T. Talarico  
Group Art Unit 1645  
Examiner Name S. Devi  
Attorney Docket Number 035780/233666

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
SD	15	US-5,234,903	08-10-1993	NHO <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
SD	16	WO 02/44214 A1	06-06-2002	Apex Bioscience, Inc.		
SD	17	WO 90/15613	12-27-1990	Rorer Int'l, Inc.		

**OTHER DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
SD	18	MATSUMURA, S., "Large Scale Production and Characterization of Lyophilized Pyridoxalated Hemoglobin-Polyoxyethylene (PHP)," <i>Biomat., Art. Cells &amp; Immob. Biotech.</i> , 1992, Vol. 20(2-4), pp. 435-438.	
SD	19	TALARICO, T.L., "Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study," <i>BioPharm</i> , 1999, Vol. 12(1), pp. 42-47.	
Examiner Signature	SD	Date Considered	Novem. 04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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The PTO did not receive the following listed items(s) Cite # 16, 17, 18, 19